PREDNISOLONE SODIUM PHOSPHATE- prednisolone sodium phosphate solution/ drops
Bausch & Lomb Incorporated

Prednisolone Sodium
Phosphate Ophthalmic
Solution, USP 1% (Sterile)

Rx only

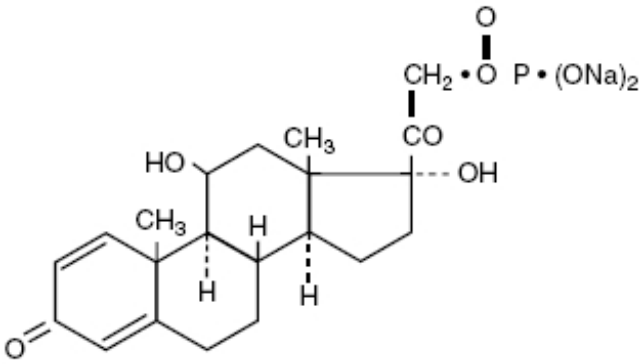
DESCRIPTION

Prednisolone Sodium Phosphate Ophthalmic Solution, 1%, is a sterile solution for ophthalmic administration having the following composition:

Each mL contains:

ACTIVE: Prednisolone Sodium Phosphate 10 mg (1%) [equivalent to 9.1 mg/mL prednisolone phosphate] in a buffered isotonic solution containing **INACTIVES:** Hypromellose, Monobasic and Dibasic Sodium Phosphate, Sodium Chloride, Edetate Disodium and Purified Water. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust the pH (6.2-8.2).
PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

The chemical name for prednisolone sodium phosphate is Pregna-1, 4-diene - 3, 20-dione, 11, 17-dihydroxy-21-(phosphonooxy)-, disodium salt, (11 β) -, which has the following structural formula:



Molecular Formula: $C_{21}H_{27}Na_2O_8P$

Molecular Weight: 484.39

CLINICAL PHARMACOLOGY

Prednisolone sodium phosphate causes inhibition of inflammatory response to inciting agents of mechanical, chemical, or immunological nature. No generally accepted explanation of this steroid property has been advanced.

INDICATIONS AND USAGE

Prednisolone Sodium Phosphate Ophthalmic Solution, 1% or 1/8% is for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation, corneal injury from chemical,

radiation, or thermal burns, or penetration of foreign bodies.

Prednisolone Sodium Phosphate Ophthalmic Solution, 1%, is recommended for moderate to severe inflammations, particularly when unusually rapid control is desired. In stubborn cases of anterior segment eye disease, systemic adrenocortical hormone therapy may be required. When deeper ocular structures are involved, systemic therapy is necessary.

CONTRAINDICATIONS

The use of this preparation is contraindicated in the presence of:

1. Acute superficial herpes simplex keratitis.
2. Fungal diseases of ocular structures.
3. Acute infectious stages of vaccinia, varicella and most other viral diseases of the cornea and conjunctiva.
4. Tuberculosis of the eye.
5. Hypersensitivity to a component of this medication.

The use of this preparation is always contraindicated after uncomplicated removal of a superficial corneal foreign body.

WARNINGS

NOT FOR INJECTION INTO EYE - FOR TOPICAL USE ONLY

Employment of steroid medication in the treatment of herpes simplex keratitis involving the stroma requires great caution; frequent slit-lamp microscopy is mandatory.

Prolonged use may result in elevated intraocular pressure and/or glaucoma, damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, or may aid in the establishment of secondary ocular infections from pathogens liberated from ocular tissues. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical steroids. Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication. Viral, bacterial, and fungal infections of the cornea may be exacerbated by the application of steroids.

This drug is not effective in mustard gas keratitis and Sjögren’s keratoconjuncitivitis.

If irritation persists or develops, the patient should be advised to discontinue use and consult prescribing physician.

PRECAUTIONS

General:

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term steroid applications, fungus invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use.

Intraocular pressure should be checked frequently.

Information for Patients:

Do not touch dropper tip to any surface as this may contaminate the solution.

Usage in Pregnancy:

Animal reproductive studies have not been conducted with prednisolone sodium phosphate. It is also not known whether prednisolone sodium phosphate can cause fetal harm when administered to a pregnant

woman or can affect reproductive capacity. Prednisolone sodium phosphate should be given to a pregnant woman only if clearly needed.

The effect of prednisolone sodium phosphate on the later growth, development and functional maturation of the child is unknown.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prednisolone sodium phosphate is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infections from pathogens including herpes simplex and fungi, and perforation of the globe.

Rarely, filtering blebs have been reported when topical steroids have been used following cataract surgery.

Rarely, stinging, or burning may occur.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Depending on the severity of inflammation, instill one or two drops of solution into the conjunctival sac up to every hour during the day and every two hours during the night as necessary as initial therapy.

When a favorable response is observed, reduce dosage to one drop every four hours.

Later, further reduction in dosage to one drop three to four times daily may suffice to control symptoms.

The duration of treatment will vary with the type of lesion and may extend from a few days to several weeks, according to therapeutic response. Relapses, more common in chronic active lesions than in self-limited conditions, usually respond to retreatment.

HOW SUPPLIED

Prednisolone Sodium Phosphate Ophthalmic Solution, USP 1% is supplied in a plastic squeeze bottle with a white cap and a controlled drop tip in the following size:

10 mL bottle - NDC 24208-715-10

Storage:

Store between 15° to 25°C (59° to 77°F).
Protect from light. Keep tightly closed.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Keep out of reach of children.

Distributed by:
Bausch + Lomb, a division of
Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Bausch & Lomb Incorporated
Tampa, FL 33637 USA

Revised: March 2020

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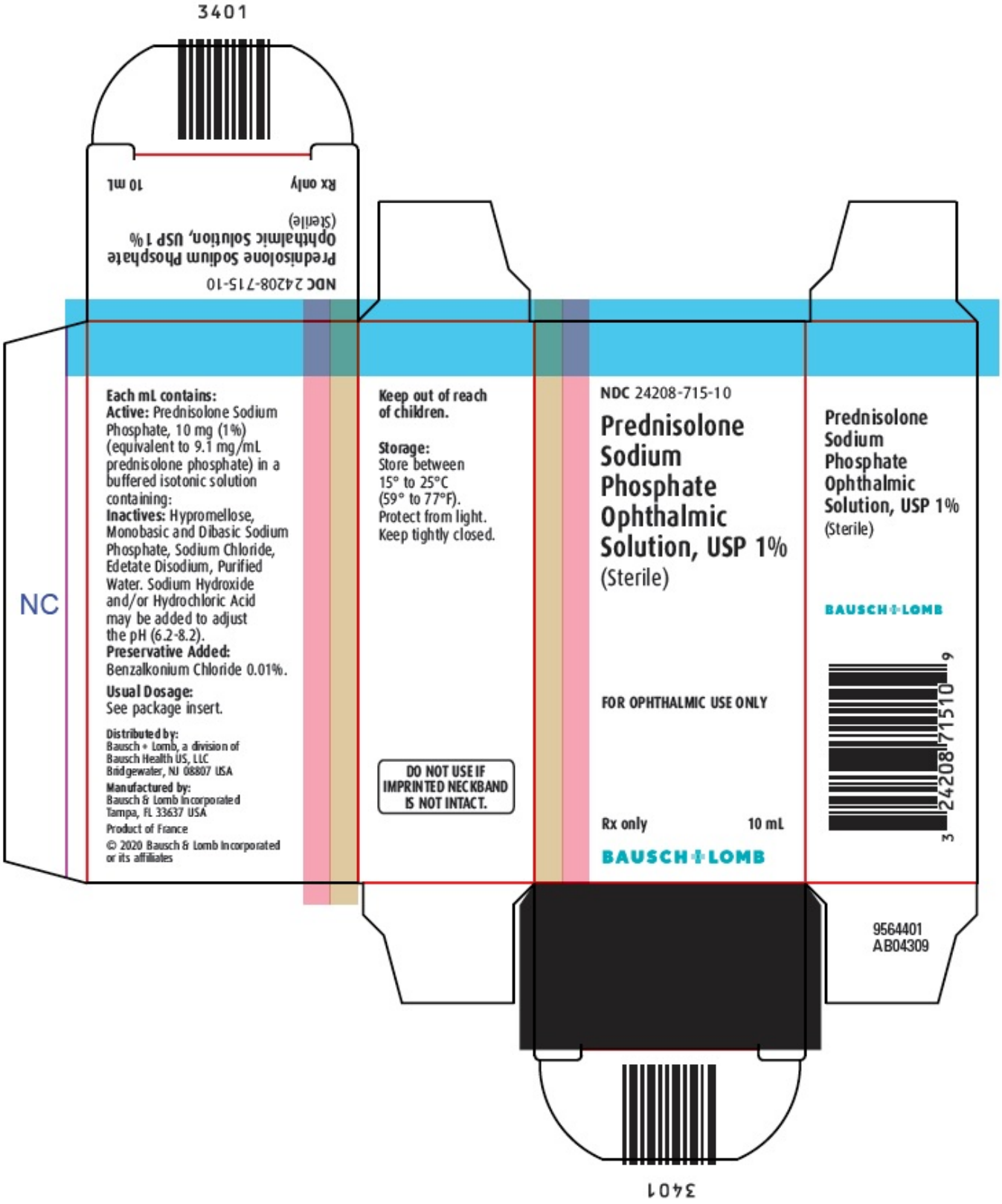
9101505 (Flat)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



NDC 24208-715-10

Prednisolone Sodium Phosphate Ophthalmic Solution USP, **1**% (Sterile)

FOR OPHTHALMIC USE ONLY

Rx only

10 mL

BAUSCH + LOMB

PREDNISOLONE SODIUM PHOSPHATE

prednisolone sodium phosphate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24208-715
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PREDNISOLONE SODIUM PHOSPHATE (UNII: IV021NXA9J) (PREDNISOLONE - UNII:9PHQ9Y1OLM)	PREDNISOLONE 21-PHOSPHATE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24208-715-02	1 in 1 CARTON	07/29/1999	10/26/2010
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:24208-715-10	1 in 1 CARTON	07/29/1999	
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:24208-715-06	1 in 1 CARTON	07/29/1999	08/20/2009
3		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040070	07/29/1994	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-715)

Revised: 3/2020 Bausch & Lomb Incorporated